DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 9, 2015

H.C. Starck Ceramics GmbH
c/o Ms. Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K143656
Trade/Device Name: StarCeram® Z-Nature, StarCeram® Z-Smile
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: June 10, 2015
Received: June 11, 2015

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143656

Device Name
StarCeram® Z-Nature
StarCeram® Z-Smile

Indications for Use *(Describe)*
Dental Blanks made from StarCeram® Z-Nature are indicated for crowns, multi-unit bridges, inlay bridges and all-ceramic restoration. Applications include both anterior and posterior bridges.

Dental Blanks made from StarCeram® Z-Smile are indicated for crowns and bridges, multi-unit bridges, inlay bridges and all-ceramic restoration as max three-unit bridge at the anterior and posterior area.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
K143656

H.C. Starck Ceramics GmbH
StarCeram®

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Maureen O'Connell
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North Reading, MA 01864
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Date Prepared: July 6, 2015

Name of Device and Name/Address of 510(k) Owner
StarCeram® Z-Nature
StarCeram® Z-Smile

H.C. Starck Ceramics GmbH
Lorenz-Hutschenreuther-Str. 81
95100 Selb, Germany

Common or Usual Name
Powder, Porcelain

Classification Name
21 C.F.R. 872.6660
Porcelain powder for clinical use

Predicate Devices
Primary Predicate
StarCeram® products cleared in K133213

Reference Predicates
StarCeram® Z-Med TransColour Red (K140924)
DD cubeX² (K150196)

Intended Use / Indications for Use
Dental Blanks made from StarCeram® Z-Nature are indicated for crowns, multi-unit bridges, inlay bridges and all-ceramic restoration. Applications include both anterior and posterior bridges.

Dental Blanks made from StarCeram® Z-Smile are indicated for crowns and bridges, multi-unit bridges, inlay bridges and all-ceramic restoration as max three-unit bridge at the anterior and posterior area.

Device Description
Dental blanks made from StarCeram® products are semi finished products made of yttrium stabilized pre-sintered zirconium dioxide for milled production of crowns and bridge framework on commercial CAD/CAM systems or hand-operated copy-milling. StarCeram® Z-Smile and StarCeram® Z-Nature are a modification to the StarCeram® products that have already been cleared by the Food and Drug Administration in K133213 and K140924. StarCeram® Z-Smile and StarCeram® Z-Nature have the same intended use and fundamental scientific technology as the StarCeram® products previously cleared by FDA. The only change between the cleared products and the new products is the addition of new color qualities.

Non-clinical Testing
Biocompatibility and cytotoxicity testing was performed which showed that all versions of the product comply with ISO 10993-1 and ISO 10993-5. Biocompatibility testing was performed under Design Controls to show that the modified version of the product continued to comply with the recognized consensus standards.

Clinical Testing
No clinical testing was performed.

Substantial Equivalence

Product Name	StarCeram® Z-Nature and Z-Smile	StarCeram® Z-Med, StarCeram® Z-Al-Med HD, StarCeram® Z-Al-Med-HD Colour, StarCeram® Z-Al-Med HD Translucent, StarCeram® Z-Med TransColour	StarCeram® Z-Med TransColour Red	DD cubeX² and accessories

510(k) Number	K143656	K133213	K140924	K150196
Product Code	EIH	EIH	EIH	EIH
Product Description	Semi finished products made of yttrium stabilized pre-sintered zirconium dioxide for milled production of crowns and bridge framework on commercial CAD/CAM systems or hand-operated copy-milling machines.	Semi finished products made of yttrium stabilized pre-sintered zirconium dioxide for milled production of crowns and bridge framework on commercial CAD/CAM systems or hand-operated copy-milling machines.	Semi finished products made of yttrium stabilized pre-sintered zirconium dioxide for milled production of crowns and bridge framework on commercial CAD/CAM systems or hand-operated copy-milling machines.	*DD cubeX2* is a semi-finished dental blank made of yttrium stabilized pre-sintered zirconium dioxide, which has a super high translucency. The ceramics is of type II (not powder), Class 5 according to DIN EN ISO 6872 (FDA Recognition Number 4-178). The *DD cubeX2* dental blanks are designed for milled production of crowns and bridge frameworks on commercial CAD/CAM systems or hand-operated copy milling machines.
Material	Yttrium stabilized zirconium dioxide	Yttrium stabilized zirconium dioxide	Yttrium stabilized zirconium dioxide	Yttrium stabilized zirconium dioxide
Availability	Various colors, translucencies and thicknesses	Various colors, translucencies and thicknesses	Various colors, translucencies and thicknesses	Various colors, translucencies and thicknesses
Flexural Strength	Z-Smile >500 Z-Nature 1,000 +/- 200	1,000 +/- 200	1,000 +/- 200	>720

H.C. Starck's StarCeram® Z-Smile and StarCeram® Z-Nature are modifications to the StarCeram® products cleared in K133213 and K140924. StarCeram® Z-Nature has the same intended use and indications for use,

principles of operation, and similar technological characteristics as the previously cleared predicate devices. StarCeram® Dental Blanks are indicated for crowns, multi-unit bridges, inlay bridges and all-ceramic restoration. Applications include anterior and posterior bridges. This is the exact indications for use statement cleared for StarCeram® in K133213 and K140924. Thus, StarCeram® Z-Nature has the same intended use and may be substantially equivalent.

StarCeram® Z-Smile is also substantially equivalent to the DD cubeX^2 cleared in K150196. StarCeram® Z-Smile has the same intended use also allowing a maximum of 3 bridges to be constructed using the product. The flexural strength of StarCeram Z-Smile is slightly lower than the predicate, but exactly as required by DIN EN ISO 6872 for Class 5 dental ceramics (>500MPa). Therefore, STARCERAM Z-Smile is substantially equivalent to the DD cubeX^2 cleared in K150196.

StarCeram® Z-Smile and StarCeram® Z-Nature have the same technological characteristics as the predicate devices. All of the devices are yttrium stabilized pre-sintered zirconium dioxide to be used in dental restorations. The StarCeram® products cleared in K133213 and K140924, and StarCeram® Z-Smile and StarCeram® Z-Nature are all dental blanks which are fabricated to the desired shape by the user based on the specific needs of the patient.